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12/470,735 06/06/95 ISRAELI FIRST NAMED INVENTOR R ATTORNEY DOCKET NO.

18M1/0108

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 CAPITA
EXAMINER

 18M1/7 ART UNIT PAPER NUMBER

01/08/97

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/470,735	Applicant(s) Israeli et al.
Examiner Anthony C. Caputa	Group Art Unit 1817



Responsive to communication(s) filed on _____.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-92 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-92 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, 14-21, 74-76 drawn to a nucleic acid encoding a prostate specific antigen, classified in class 536, subclass 23.5.
 - II. Claims 12 and 13, drawn to a method of detecting said antigen with said nucleic acid, classified in class 435, subclass 6.
 - III. Claims 23, 27, 28, 29, 31 drawn to a ligand, classified in class 530, subclass 350.
 - IV. Claim 22, drawn to a method of using the ligand to determine if said ligand binds to the antigen, classified in class 435, subclass 7.2.
 - V. Claims 24 and 25, drawn to the prostate specific antigen, classified in class 530, subclass 350.
 - VI. Claims 26, drawn to a method of making a ligand, classified in class 530, subclass 412.
 - VII. Claim 30, drawn to a method of using the ligand for imaging the prostate cancer, classified in class 435, subclass 7.2.
 - VIII. Claims 32-36, drawn to a antibody, classified in class 530, subclass 387.7.
 - IX. Claims 37 and 38, drawn to a therapeutic agent comprising said antibody and cytotoxic agent, classified in class 424, subclass 138.1.

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- X. Claims 39-45, drawn to a method of detection using said antibody and composition comprising said antibody and carrier (or radioisotope), classified in class 435, subclass 7.1.
- XI. Claim 46, drawn to a method of purifying said antigen, classified in class 530, subclass 412.
- XII. Claims 47 and 48 drawn to a transgenic mammal classified in class 800, subclass 2.
- XIII. Claim 49-72, 77, 84-89 drawn to a method of treatment using the nucleic acid said antigen, classified in class 514, subclass 44.
- XIV. Claims 78-83, 90-92 drawn to a method of detection using primers of said antigen, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

- A. Groups I, II, XII, XIII, and XIV drawn to a nucleic acid and Group III, IV, V, VI, VII, VIII, IX, X, and XI, drawn to antigens, antibodies, and ligands are distinct inventions since they are drawn to product with different structure and biological properties.
- B. Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the DNA can be used for treatment.

C. Group I and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA can be used for detection by mRNA hybridizing to the nucleic acid molecule.

D. Group I and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA can be used for treatment.

E. Group I, II, XIII, XIV drawn to a nucleic acid and Group XII drawn to transgenic animal are distinct inventions since they are drawn to product with different structure and biological properties. Furthermore the method of making the DNA of Group I, II, XIII, and XIV does not require the transgenic animal of Group XII.

F. Group II, drawn to a method of detecting said antigen is distinct from Group XIII, and XIV since the methods of each group require different reagents and parameters.

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G. Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ligand can be used for imaging prostate cancer.

H. Group III and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ligand can be used to determine if the ligand binds to the antigen.

I. Groups VI and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed to make antibodies.

J. Group III, IV, VI, VII drawn to a ligand is distinct from Group V, VIII, IX, X, XI, XII, XIII, and XIV drawn to antigens, antibodies, and transgenic animals since they are drawn to product with different structure and biological properties.

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K. Groups IV, VI, VII are distinct from each other since the methods require different parameters and reagents.

L. Group V and XI drawn to an antigen is distinct from Group VIII, IX, X, XII, XIII, and XIV drawn to antibodies, and transgenic animals since they are drawn to products with different structure and biological properties.

M. Groups XI and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein can be made by recombinant means or Merrifield chemical synthesis.

N. Group VIII and Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used for detection.

O. Group VIII and Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used for treatment.

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P. Groups IX and X are distinct from each other since the methods require different parameters and reagents.

Q. Groups XIII and XIV are distinct from each other since the methods require different parameters and reagents.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. A telephone call was made to J. White to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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Anthony C. Caputa, Ph.D.

January 6, 1996

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